RESEARCH SCOPE OF PRACTICE
West Palm Beach VAMC (548)
R&D Service (142)

I. PURPOSE:

The Scope of Practice is specific to the duties and responsibilities of each research employee/staff. The employee is specifically authorized to conduct research involving human subjects with the responsibilities outlined below in conjunction with approved research protocols. This document does not waive the responsibility to secure West Palm Beach VA Medical Center (WPBVAMC) Clinical Credentialing & Privileging for any licensed independent provider under VHA Directive 1100.19 or other appropriate institutional privileging directives. This document is consistent with VHA policy that all individuals must have the appropriate training, education, expertise, and credentials to conduct the research according to the research protocol, including those individuals who do not function as health care providers. The Scope of Practice Statement must be consistent with the position to which the individual is appointed and must define the duties of the individual. This Scope of Practice Statement must not include any duties or procedures for which the individual is not qualified. If the individual holds clinical privileges at WPBVAMC the duties must not exceed clinical privileges. If there are additional research responsibilities and duties, these should be included in this Scope of Practice Statement and be verified by the supervisor or principal investigator. The Principal Investigator and/or Supervisor must complete this form with the employee once every 3 years and submit it to the R&D Service for review by the ACOS/R before the research employee/staff is allowed to start on a participating research project.

II. Researcher Information:

Name	Job Title and Service
Licensure	Degree
Supervisor/Supervising Investigator Name #1:	Job Title and Service
Supervisor/Supervising Investigator Name #2:	Job Title and Service
Supervisor/Supervising Investigator Name #3:	Job Title and Service

RESEARCH SCOPE OF PRACTICE
West Palm Beach VAMC (548)
R&D Service (142)

III. SCOPE OF DUTIES:

General Duties (Check all that apply; some may require competencies or credentials) ****NOTE: All study specific required training must be documented in the regulatory files*	Check all that apply
Protocol & Regulatory Documentation:	
Prepares and maintains complete and accurate records (e.g. data collection records, source documents, case report forms, screening logs and/or procedural/surgical records, etc.)	☐
Prepares regulatory documents for R&D Committees and/or Sponsors	☐
Participates in designing and/or the implementation of research protocols	☐
Prepares site initiation activities	☐
Prepares and/or manages budgets	☐
Prepares orders for laboratory, clinical or other project supplies	☐
Obtains and organizes data such as tests results, diaries/cards or other necessary information	☐
Compiles data for analysis	☐
Prepares publications and/or presentations	☐
Specimens: N/A: ☐ Not authorized to collect or handle specimens	
Uses and/or is knowledgeable about the handling of containment equipment (e.g. personal protective clothing and equipment, safety cabinets, eye wash stations, etc.)	☐
Uses and/or is knowledgeable about the handling of biomaterials, microbial or viral agents, pathogens, and/or toxins	☐
Collects specimens per protocol, including blood, urine, sputum, buccal swabs, etc. (requires competency verification by observation by an individual with appropriate credentials)	☐
Processes and ships biological specimens as indicated in the research protocol (must meet DOT requirements and requires IATA training)	☐
Performs non-exempt molecular biology experiments as defined in the NIH guidelines for research involving recombinant and/or synthetic DNA molecules	☐
Chemicals: N/A: ☐ Not authorized to collect or handle chemicals	
Uses and/or is knowledgeable about the handling of containment equipment (e.g. personal protective clothing and equipment, safety cabinets, eye wash stations etc.)	☐
Uses and/or is knowledgeable about the handling, storage, and disposal of chemicals (e.g. toxic, carcinogenic, flammable, etc.)	☐

RESEARCH SCOPE OF PRACTICE
West Palm Beach VAMC (548)
R&D Service (142)

General Duties (Check all that apply; some may require competencies or credentials)	Check all that apply
Uses and is knowledgeable about the handling of radioactive materials and/or radiation generating equipment. (Radiation Safety approval required to order/use radioactive materials)	☐
Equipment: N/A: ◯ Not authorized to operate equipment	☐
Uses and is familiar with the safe operation of routine laboratory equipment including but not limited to centrifuges, safety cabinets, exhaust hoods, etc. (Requires completion of the relevant training)	☐
Clinical Duties: N/A: ◯ Not authorized for clinical	☐
Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing patients	☐
Obtains informed consent from research participant (requires knowledge and application of informed consent process and competency verification through observation by an individual with appropriate credentials)	☐
Provides education and instruction regarding study activities to patient, relatives, and VHA staff as necessary	☐
Schedules participant research visits and study procedures	☐
Provides participant education and instruction on the use of study drug, device or equipment (non-licensed individuals require competency verification through observation by an individual with appropriate credentials)	☐
Reports laboratory results and other diagnostic testing (e.g., radiography, clinical pathology) to PI, study sponsor and/or appropriate personnel in a timely manner)	☐
Obtains information and/or data from patients that are pertinent to a research protocol (may be from CPRS, questionnaires or direct interaction)	☐
Enters research progress notes into CPRS under appropriate headings or titles	☐
Prepares/manages payments to research participants	☐
Obtains and records vital signs (non-licensed individuals require competency verification through observation by an individual with appropriate credentials)	☐
Orders, alters, or adjusts inpatient and outpatient medications or investigational drugs (within limits of license)	☐

RESEARCH SCOPE OF PRACTICE
West Palm Beach VAMC (548)
R&D Service (142)

Clinical Duties **(Check all that apply; some may require competencies or credentials)**	**Check all that apply**
Provides study medication from pharmacist, per a licensed providers order, to participant (non-licensed individuals require competency verification through observation by an individual with appropriate credentials) ******NOTE: Research drugs/medications must be handled and/or coordinated per WPBVAMC Research Pharmacy policy and a pharmacist***	☐
Performs venipuncture to obtain specific specimens required by study protocol (non-licensed individuals require competency verification through observation by an individual with appropriate credentials)	☐
Evaluates health problems, including possible adverse events (within limits of license, non-licensed individuals require competency verification through observation by an individual with appropriate credentials)	☐
Performs physical examination (within limits of license, non-licensed individuals require competency verification through observation by an individual with appropriate credentials)	☐
Performs physical assessment (within limits of license, non-licensed individuals require competency verification through observation by an individual with appropriate credentials)	☐
Establishes intravenous (IV) access (within limits of license)	☐
Administers intravenous (IV) solutions and medications (within limits of license)	☐
<u>Other Duties:</u> (not covered above):	

IV. RESEARCH EMPLOYEE'S STATEMENT:

This Scope of Practice outlines general tasks I am permitted to undertake in conjunction with approved protocols. I understand that all research must be approved by the appropriate R&D Committees and research performed at WPBVAMC requires written approval of the ACOS/R. If I have questions or concerns, I am encouraged to contact the WPBVAMC Research Office. I also understand that performing tasks beyond this scope of practice, without specific authorization, may lead to disciplinary action. Both my supervisor or supervising investigator and I are familiar with all duties and procedures granted in this Scope of Practice. I agree to abide by the parameters of this Scope of Practice and all-applicable facility policies and regulations.

Have there been changes in research duties made since your last submission? NO ☐ YES ☐ N/A (Initial) ☐

If yes to the above question, please explain here:

Date: _____

_____
Research Employee Signature

_____
Name of Research Employee
[Last name, First name] – Printed

V. SUPERVISOR OR SUPERVISING INVESTIGATOR STATEMENT:

The foregoing Scope of Practice was reviewed and discussed with the employee on the date shown below. After reviewing the education, competencies, qualifications, experience, and individual skills I certify that this employee possesses the skills to safely perform the aforementioned duties and procedures. Both the employee and I are familiar with all duties and procedures granted in this Scope of Practice. We agree to abide by the parameters of this Scope of Practice, and all-applicable facility policies and regulations. I further understand that conducting research at WPBVAMC without the required committee approvals may affect an individual's standing at the institution and that ethical breaches in the conduct of research may affect an individual's ability to do research with the institution in the future.

This Scope of Practice will be reviewed at least every 3 years (or whenever changes are required) and a new Scope of Practice form will be submitted to the R&D Office. If amendments are needed to reflect changes in the research employee's duties or responsibilities a new Scope of Practice will be signed by the ACOS/R before the employee commences with any new duties.

****Note:** *If the protocol specifically states that certain tasks must be performed by the PI, the PI may not delegate those tasks.*

_____
Primary Supervisor/Supervising Investigator Signature

Date: _____

_____
Name of Supervisor/Supervising Investigator
[Last name, First name]

VI. ACOS/R REVIEW:

The foregoing Scope of Practice was reviewed by me.

_____ Date:_____

ACOS Research and Development Signature

Cuevas-Trisan, Ramon, MD_

Name of ACOS/R [Last name, First name]